Rule Summary and Fiscal Analysis (Part A)

Department of Agriculture

Agency Name

Food Safety Division David E Miran Contact

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<u>901:3-23-01</u>

AMENDMENT

Rule Number

TYPE of rule filing

Rule Title/Tag Line

Criteria and definitions for juice products.

RULE SUMMARY

1. Is the rule being filed for five year review (FYR)? Yes

2. Are you proposing this rule as a result of recent legislation? No

3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**

4. Statute(s) authorizing agency to adopt the rule: **3715.02**; **3715.021**

5. Statute(s) the rule, as filed, amplifies or implements: **3715.27**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

This rule is being proposed pursuant to the five year rule review process. The rule has been amended after members of the industry requested a change that would allow them to expand their business models.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

Ohio Administrative Code 901:3-23-01 and the rules of that chapter regulate the processing of juice products in the state of Ohio. Without proper safeguards, the juice manufacturing process can result in the growth of highly dangerous pathogens such as Clostridium botulinum, E. coli 0157:H7, Salmonella, and Listeria monocytogenes. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting and in some cases can result in the death of the infected individual. Due to this high level of risk there is significant regulation to monitor the juice production industry which is designed to prevent illness and protect consumers.

901:3-23-01 sets for the criteria and definitions of juice products. This rule outlines the definitions to be used in Ohio Administrative Code Chapter 901:3-23 as well as defines the food processing establishments that are subject to the rules of the chapter. The rule is being amended to clarify the establishments who are exempt from this chapter.

Prior to the proposed amendment, the chapter excluded #a retail food establishment or food service operation defined in section 3717.01 of the Revised Code where the juice produced is only sold or served from that premises.# This allowed companies to produce raw, unpasteurized juice for consumers so long as it was produced at the site where it was sold. The Ohio Department of Agriculture (hereinafter #Department#) was contacted by several raw juice producers looking to expand their business however, were unable to as they were limited by the rule.

In order to accommodate these growing businesses, the Department has proposed to amend the rule to allow these companies to utilize a #central kitchen# model. This model would allow the raw juice companies to produce their product in a central kitchen and deliver it to their own establishments. Prior to the proposed amendment each new establishment was required to possess separate production equipment. This equipment costs thousands of dollars and limited each company#s ability to expand. With the proposed amendment, businesses would now be able to expand without the excessive cost of the additional equipment.

The rule only allows these facilities to deliver their products to either a licensed food service operation or retail food establishment which is licensed under the same name. This ensures that the product is controlled by the company itself which understands and monitors the shelf-life, safety, and quality of the products. This is important due to the food safety risks when dealing with unpasteurized juice. As stated above, without proper safeguards, the juice manufacturing process can result in the grown of potentially deadly bacteria.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected

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by the rule, provide an explanation of how the text or other material is generally available to those persons:

Pursuant to section 121.76 of the Revised Code, the code sections incorporated into this rule are exempt from compliance with sections 121.71 to 121.74 of the Revised Code

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Not applicable.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. Five Year Review (FYR) Date: 10/27/2015

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department. This will have no impact on revenues or expenditures.

\$0.00

Not applicable.

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable.

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

The cost to register as a food processing establishment depends on the square footage of the facility. A majority of Ohio#s juice processors who register as a food processing establishment fall under the smallest category which is below 5000 square feet. The cost of this registration is \$50 annually. The largest facilities, over 100,000 square feet, must pay \$300 annually to register as a food processing establishment.

The adverse impact of these regulations is difficult to quantify as it is hard to separate production practices from regulation. The regulations dictate some equipment specifications; however equipment manufacturers specifically tailor their machinery to meet the regulations. Additionally, there are record keeping requirements which require time for employer compliance however; for the most part the machinery used in this industry automatically records this information.

Prohibiting the transportation of juice to a separate, unaffiliated establishment would limit the market share of the company. The quantified cost of this is unknown.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? No

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? No

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? Yes

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19. Specific to this rule, answer the following:

A.) Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? Yes

All food processing establishments must be registered with the Department. This requirement is pursuant to 3715.041 of the Revised Code.

B.) Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? Yes

Failure to register as a food processing establishment or failure to follow the rules of this chapter may result in any food produced by an establishment to be considered adulterated which would subject that food product to possible condemnation.

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? No